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Sheet 1 of 6 06132/075002 Attorney Docket No. U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE SUBSTITUTE FORM PTO-1449 (MODIFIED) Serial No. 10/715,868 Applicant Juan Arroyo et al. INFORMATION DISCLOSURE November 17, 2003 Filing Date STATEMENT BY APPLICANT (Use several sheets if necessary)

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U.S. PATENT DOCUMENTS				
Examiner's Initials	Document Number	Publication Date/Filing Date	Patentee or Applicant	
	6,171,854	Jan. 9, 2001	Galler and Freire	
	6,962,708	Nov. 8, 2005	Chambers et al.	
	2003/0044773	Mar. 6, 2003	Kleanthous et al	
	2003/0194801	Oct. 16, 2003	Bonaldo et al.	
•	2004/0223979	Nov. 11, 2004	Chambers et al.	
,	2004/0259224	Dec. 23, 2004	Guirakhoo	
	2005/0002968	Jan. 6, 2005	Monath et al.	
-	2007/184469	Aug. 9, 2007	Depres and Catteau	
	08/807,445	Feb. 28, 1997	Chambers et al.	
	09/007,664	Jan. 15, 1998	Chambers et al.	

	FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION					
Examiner's Initials	Document Number	Publication Date		Country or Patent Office		Translation (Yes/No)
	WO 02/072835	Sept. 19, 2002	٧	V.I.P.O.		
	WO 02/102828	Dec. 27, 2002	٧	V.I.P.O.		
	WO 03/101397	Dec. 11, 2003	V	V.I.P.O.		
	WO 03/103571	Dec. 18, 2003	V	V.I.P.O.		
· · · · · · · · · · · · · · · · · · ·	WO 04/045529	Jun. 3, 2004	ľ	V.I.P.O.		
	WO 05/040390	May 6, 2005	\	V.I.P.O.		No
	WO 05/049815	Jun. 2, 2005	1	V.I.P.O.		
	WO 05/082020	Sept. 9, 2005	\	V.I.P.O.		
EXAMINER				DATE CONSIDERED		

(37 C.F.R. § 1.98(b))		IDS Filed	October 11, 2007
(Use several sheets if necessary)		Group	1648
STATEMEN	ON DISCLOSURE T BY APPLICANT	Filing Date	November 17, 2003
INFORMATION	ON DISCLOSURE	Applicant	Juan Arroyo et al.
(MODIFIED)	PATENT AND TRADEMARK OFFICE	Serial No.	10/715,868
SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE	Attorney Docket No.	06132/075002

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
	WO 06/044857	Apr. 27, 2006	W.I.P.O.	·
	WO 06/116182	Nov. 2, 2006	W.I.P.O.	
	WO 07/051267	May 10, 2007	W.I.P.O.	

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
Bancroft, "Current Status of Dengue Vaccines and Prospects for the Future," <i>Puerto Rico Health Sci. J.</i> 6(1):23-26, 1987. Abstract only.
Barrett, "Current Status of Flavivirus Vaccines," Ann. N. Y. Acad. Sci. 951:262-271, 2001.
Bonaldo et al., "The Yellow Fever 17D Vaccine Virus as a Vector for the Expression of Foreign Proteins: Development of New Live Flavivirus Vaccines," <i>Mem. Inst. Oswaldo Cruz, Rio de Janeiro</i> 95(Suppl. 1):215-223, 2000.
Bonaldo et al., "Surface Expression of an Immunodominant Malaria Protein B Cell Epitope by Yellow Fever Virus," <i>J. Mol. Biol.</i> 315:873-885, 2002.
Bonaldo et al., "Attenuation of Recombinant Yellow Fever 17D Viruses Expressing Foreign Protein Epitopes at the Surface, " <i>J. Virology</i> 79:8602-8613, 2005.
Bonaldo et al., "Expression of Foreign Protein Epitopes at the Surface or Recombinant Yellow Fever 17D Viruses Based on Three-Dimensional Modeling of Its Envelope Protein," Cell Biochem. Biophys. 44:313-324, 2006.
Bray et al., "Genetic Determinants Responsible for Acquisition of Dengue Type 2 Virus Mouse Neurovirulence," J. Virology 72:1647-1651, 1998.
Cardosa, "Dengue Vaccine Design: Issues and Challenges," British Med. Bull. 54(2):395-405, 1998.
Carle et al., "Experiments on the Transmission of an Icterogenic Agent in Yellow Fever Vaccine to Horses and Swine," <i>J. Bacteriol.</i> 48:45-69, 1944.
Chen et al., "Generation and Characterization of Organ-Tropism Mutants of Japanese Encephalitis Virus In Vivo and In Vitro," Virology 223:79-88, 1996.
Dermime et al., "Vaccine and Antibody-Directed T Cell Tumour Immunotherapy," <i>Biochim. Biophys. Acta</i> 1704:11-35, 2004.
De Vries et al., "Genetic Manipulation of Equine Arteritis Virus Using Full-Length cDNA Clones: Separation of Overlapping Genes and Expression of a Foreign Epitope," <i>Virology</i> 270:84-97, 2000.

EXAMINER	DATE CONSIDERED

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No. Serial No.	06132/075002 10/715.868
INFORMATIO	ON DISCLOSURE	Applicant	Juan Arroyo et al.
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(655 551512) 5116615 11 11655522.37		Group	1648
(37 C.F.R. § 1.98(b))		IDS Filed	October 11, 2007

And the second s
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
dos Santos et al., "Determinants in the Envelope E Protein and Viral RNA Helicase NS3 that Influence the Induction of Apoptosis in Response to Infection with Dengue Type 1 Virus," <i>Virology</i> 274:292-308, 2000.
Edelman et al., "Phase I Trial of 16 Formulation of a Tetravalent Live-Attenuated Dengue Vaccine," Am. J. Trop. Med. Hyg. 69(Suppl 6):48-60, 2003.
EZ::TN™ Insertion System (Epicentre).
Goryshin and Reznikoff, "Tn5 In Vitro Transposition," J. Biol. Chem. 273:7367-7374, 1998.
Guirakhoo et al., "Recombinant Chimeric Yellow Fever-Dengue Type 2 Virus is Immunogenic and Protective in Nonhuman Primates," <i>J. Virology</i> 74:5477-5485, 2000.
Guirakhoo et al., "Construction, Viremia, and Immunogenicity Profile of Recombinant Chimeric Yellow Fever/Dengue Viruses in Nonhuman Primates," Program and Abstracts of the 49 <sup>th</sup> Annual Meeting of the American Society of Tropical Medicine and Hygiene, Houston, Texas, October 29-November 2, 2000, Supplement to <i>Am. J. Trop. Med. Hyg.</i> , 313, Abstract.
Guirakhoo et al., "Construction, Viremia, and Immunogenicity Profile of Recombinant Chimeric Yellow Fever/Dengue Viruses in Nonhuman Primates," Program and Abstracts of the 49 <sup>th</sup> Annual Meeting of the American Society of Tropical Medicine and Hygiene, Houston, Texas, October 29-November 2, 2000, Supplement to <i>Am. J. Trop. Med. Hyg.</i> , 1722, Abstract.
Guirakhoo et al., "Development of ChimeriVax <sup>TM</sup> -Yellow Fever Based Vaccines for Dengue and Japanese Encephalitis Viruses," 6 <sup>th</sup> International Symposium on Positive Strand RNA Viruses, Paris, May 28-June 2, 2001, Abstract.
Guirakhoo et al., "Viremia and Immunogenicity in Nonhuman Primates of a Tetravalent Yellow Fever-Dengue Chimeric Vaccine: Genetic Reconstructions, Dose Adjustment, and Antibody Responses Against Wild-Type Dengue Virus Isolates," Virology 298:146-159, 2002.
Guirakhoo et al., "Safety and Efficacy of Chimeric Yellow Fever-Dengue Virus Tetravalent Vaccine Formulations in Nonhuman Primates," <i>J. Virology</i> 78(9):4761-4775, 2004.
Guirakhoo et al., "A Single Amino Acid Substitution in the Envelope Protein of Chimeric Yellow Fever-Dengue 1 Vaccine Virus Reduces Neurovirulence for Suckling Mice and Viremia/Viscerotropism for Monkeys," <i>J. Virology</i> 78(18):9998-10008, 2004.
Guirakhoo et al., "Live Attenuated Chimeric Yellow Fever Dengue Type 2 (ChimeriVax™-DEN2) Vaccine: Phase I Clinical Trial for Safety and Immunogenicity," <i>Human Vaccines</i> 2(2):60-67, 2006.
Guy et al., "Evaluation by Flow Cytometry of Antibody-Dependent Enhancement (ADE) of Dengue Infection by Sera from Thai Children Immunized with a Live-Attenuated Tetravalent Dengue Vaccine," <i>Vaccine</i> 22:3563-3574, 2004.
Halstead and Deen, "Rapid Review: The Future of Dengue Vaccines," The Lancet 360:1243-1245, 2002.

EXAMINER	DATE CONSIDERED

SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMER		
(MODIFIED) PATENT AND TRADEMARK OFF	ICE   Serial No. 10/715,868	
	Applicant Juan Arroyo et	al.
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date November 17,	2003
(Use several sheets if necessary)	Group 1648	
(37 C.F.R. § 1.98(b))	IDS Filed October 11, 20	07

	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
	Hurrelbrink and McMinn, "Attenuation of Murray Valley Encephalitis Virus by Site-Directed Mutagenesis of the Hinge and Putative Receptor-Binding Regions of the Envelope Protein," <i>J. Virology</i> 75:7692-7702, 2001.
-	Innis and Eckels, "Progress in Development of a Live-Attenuated, Tetravalent Dengue Virus Vaccine by the United States Army Medical Research and Materiel Command," <i>Am. J. Trop. Med. Hyg.</i> 69(Suppl 6):1-4, 2003.
	Kanesa-thasan et al., "Safety and Immunogenicity of Attenuated Dengue Virus Vaccines (Aventis Pasteur) in Human Volunteers," <i>Vaccine</i> 19:3179-3188, 2001.
	Kolaskar and Kulkrani-Kale, "Prediction of Three-Dimensional Structure and Mapping of Conformational Epitopes of Envelope Glycoprotein of Japanese Encephalitis Virus," Virology 261:31-42, 1999.
	Kurane et al., "Immunity and Immunopathology in Dengue Virus Infections," Sem. Immunol. 4(2):121-127, 1992. Abstract only.
	Lai and Monath, "Chimeric Flaviviruses: Novel Vaccines Against Dengue Fever, Tick-Borne Encephalitis, and Japanese Encephalitis," Adv. Virus Res. 61:469-509, 2003.
-	Laoprasopwattana et al., "Dengue Virus (DV) Enhancing Antibody Activity In Preillness Plasma does not Predict Subsequent Disease Severity or Viremia in Secondary DV Infection," <i>J. Infect. Dis.</i> 192:510-519, 2005. Erratum in <i>J. Infect. Dis.</i> 192:1863, 2005.
	Lee et al., "Changes in the Dengue Virus Major Envelope Protein on Passaging and Their Localization on the Three-Dimensional Structure of the Protein," Virology 232:281-290, 1997.
	Li et al., "Chimeric Influenza Virus Induces Neutralizing Antibodies and Cytotoxic T Cells Against Human Immunodeficiency Virus Type 1," <i>J. Virology</i> 67(11):6659-6666, 1993.
	McAllister et al., "Recombinant Yellow Fever Viruses are Effective Therapeutic Vaccines for Treatment of Murine Experimental Solid Tumors and Pulmonary Metastases," <i>J. Virology</i> 74(19):9197-9205, 2000.
	McMinn, "The Molecular Basis of Virulence of the Encephalitogenic Flaviviruses," J. Gen. Virology 78:2711-2722 1997.
	Modis et al., "A Ligand-Binding Pocket in the Dengue Virus Envelope Glycoprotein," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 100(12):6986-6991, 2003.
400	Monath et al., "Recombinant, Chimaeric Live, Attenuated Vaccine (ChimerVax <sup>TM</sup> ) Incorporating the Envelope Genes of Japanese Encephalitis (SA14-14-2) Virus and the Capsid and Nonstructural Genes of Yellow Fever (17D) Virus is Safe, Immunogenic and Protective in Non-Human Primates," <i>Vaccine</i> 17:1869-1882, 1999.
	Monath, "Molecular Distinctions Between Attenuated (Vaccine) and Virulent Yellow Fever Viruses," In, Plotkin S/ and Orenstein WA (eds.), Vaccines, 3 <sup>rd</sup> edition, Saunders (Philadelphia), pp. 815-879, 1999.

EXAMINER	DATE CONSIDERED

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE	Attorney Docket No.	06132/075002
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		Group	1648
(37 C.F.R. § 1.98(b))		IDS Filed	October 11, 2007

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
Monath et al., "Yellow Fever 17D as a Vector for Vaccines Against Heterologous Flaviviruses," American Society for Virology, 19 <sup>th</sup> Annual Meeting, Colorado State University, Fort Collins, Colorado, July 8-12, 2000, Abstract W17-7, p. 85.
Monath, "Yellow Fever: an Update," Lancet Infect. Dis. 1:11-20, 2001.
Monath et al., "Single Mutation in the Flavivirus Envelope Protein Hinge Region Increases Neurovirulence for Mice and Monkeys but Decreases Viscerotropism for Monkeys: Relevance to Development and Safety Testing of Live, Attenuated Vaccines," <i>J. Virology</i> 76:1932-1943, 2002.
Morens and Halstead, "Measurement of Antibody-Dependent Infection Enhancement of Four Dengue Virus Serotypes by Monoclonal and Polyclonal Antibodies," <i>J. Gen. Virol.</i> 71(12):2909-2914, 1990.
Pervikov, "Development of Dengue Vaccine," W.H.O. Dengue Bulletin 24, 2000.
Rey et al., "The Envelope Glycoprotein From Tick-Borne Encephalitis Virus at 2A Resolution," <i>Nature</i> 375:291-298, 1995.
Rey, "Dengue Virus Envelope Glycoprotein Structure: New Insight Into Its Interactions During Viral Entry," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 100(12):6899-6901, 2003.
Rothman, "Dengue: Defining Protective Versus Pathologic Immunity," J. Clin. Invest. 113(7):946-951, 2004.
Ryman et al., "Yellow Fever Virus Envelope Protein has Two Discrete Type-Specific Neutralizing Epitopes," <i>J. Gen. Virology</i> 78:1353-1356, 1997.
Sabchareon et al., ""Safety and Immunogenicity of Tetravalent Live-Attenuated Dengue Vaccines in Thai Adult Volunteers: Role of Serotype Concentration, Ratio, and Multiple Doses," <i>Am. J. Trop. Med. Hyg.</i> 66:264-272, 2002.
Stephenson, "Flavivirus Vaccines," Vaccine 6(6):471-480, 1988. Abstract only.
 Sun et al., "Vaccination of Human Volunteers with Monovalent and Tetravalent Live-Attenuated Dengue Vaccine Candidates," Am. J. Trop. Med. Hyg. 69(Suppl 6):24-31, 2003.
Theiler and Smith, "The Use of Yellow Fever Virus Modified by In Vitro Cultivation for Human Immunization," Rev. Med. Virol. 10:3-16, 2000.
Vlaycheva et al., "Yellow Fever 17D Virus: Pseudo-Revertant Suppression of Defective Virus Penetration and Spread by Mutations in Domains II and III of the E protein," <i>Virology</i> 327:41-49, 2004.
Volk et al., "Solution Structure and Antibody Binding Studies of the Envelope Protein Domain III from the New York Strain of West Nile Virus," <i>J. Biol. Chem.</i> 279:38755-38761, 2004.
Wang et al., "Comparison of the Genomes of the Wild-Type French Viscerotropic Strain of Yellow Fever Virus with its Vaccine Derivative French Neurotropic Vaccine," <i>J. Gen. Virology</i> 76:2749-2755, 1995.

EXAMINER	DATE CONSIDERED
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SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE	Attorney Docket No.	06132/075002
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(37 C.F.R. § 1.98(b))		IDS Filed	October 11, 2007

- "	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
	Yamshchikov et al., "An Attenuated West Nile Prototype Virus is Highly Immunogenic and Protects Against the Deadly NY99 Strain: A Candidate for Live WN Vaccine Development," <i>Virology</i> , 330:304-312, 2004.
	International Search Report from WO02/102828 dated April 18, 2003.
	International Search Report from WO03/063725 dated June 25, 2003.
	International Search Report from WO03/101397 dated September 4, 2003.
	International Search Report from WO03/103571 dated December 12, 2003.
	International Search Report from WO04/045529 dated June 28, 2004.
	International Search Report from WO05/082020 dated September 30, 2005.
	International Search Report from WO06/044857 dated May 30, 2006.
	International Search Report from WO06/116182 dated July 17, 2006.
	European Search Report from European Application No. 05012770.

EXAMINER	DATE CONSIDERED
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